Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States

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Ibalizumab-uiyk (Trogarzo, IBA)

(Last updated December 7, 2018, last reviewed December 7, 2018)

There are insufficient human data on the use of ibalizumab during pregnancy to inform a drug-associated risk determination for birth defects and miscarriage.

Animal studies

Carcinogenicity

Carcinogenesis and mutagenesis toxicology studies of ibalizumab have not been conducted.[1]

Reproduction/Fertility

Reproductive toxicology studies of ibalizumab have not been conducted.[1]

Teratogenicity/Adverse Pregnancy Outcomes

Early embryonic development and embryo-fetal development studies with ibalizumab have not been conducted.

Placental and Breast Milk Passage

No animal data on placental or breast milk passage are available for ibalizumab.

Human Studies in Pregnancy

Pharmacokinetics

No pharmacokinetic studies of ibalizumab have been reported in pregnant women.

Placental and Breast Milk Passage

No data are available on placental or breast milk passage of ibalizumab in humans. However, since monoclonal antibodies are transported across the placenta during pregnancy, ibalizumab has the potential to be transmitted from the mother to the developing fetus. Human IgG is also present in human milk, although published data indicate that antibodies in breast milk do not enter the neonatal or infant circulation system in substantial amounts.[1]

Teratogenicity/Adverse Pregnancy Outcomes

No data are available to inform the risk determination for birth defects following exposure to ibalizumab.

Excerpt from Table 10[a]

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy
Ibalizumab-uiyk (IBA) *Trogarzo*	IBA (Trogarzo): • Solution for IV infusion is available in single-dose vials	Standard Adult Dose • IBA 2000-mg loading dose, followed by IBA 800-mg maintenance doses administered every 2 weeks Dosing in Pregnancy: • Insufficient data are available to make dosing recommendation. PK in Pregnancy: • No PK studies have been reported in human pregnancy.	No data are available, but placental transfer of IBA, a monoclonal antibody, is possible. Insufficient data are available to assess for teratogenicity in humans.

[a] Individual ARV drug dosages may need to be adjusted in patients with renal or hepatic insufficiency (for details, see the Adult and Adolescent Guidelines, Appendix B, Table 8).

Key to Acronyms: ARV = antiretroviral; IBA = ibalizumab; IV = intravenous; PK = pharmacokinetic

References

1. Ibalizumab-uiyk [package insert]. Food and Drug Administration. 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761065lbl.pdf.